Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of sexual counseling based on the BETTER model on sexual function and sexual dysfunctional beliefs in postmenopausal women referred to comprehensive health services affiliated to Shahid Beheshti University of Medical Sciences

Protocol summary

Study aim
Determining the effect of sexual counseling based on the BETTER model on sexual functioning and dysfunctional sexual beliefs in postmenopausal women

Design
The present study is a clinical trial with pre-test and post-test design with control group. The groups are parallel and the allocation of samples in two groups of 53 will be done randomly.

Settings and conduct
This study will be performed on 106 menopausal women under the comprehensive health service centers affiliated to Shahid Beheshti University of Medical Sciences. Two centers will be randomly selected and will be randomly assigned to the control and intervention groups. The intervention group will receive two individual counseling sessions of 60 to 90 minutes with an interval of 1 week. The control group will receive usual menopausal care and a pamphlet prepared by the research team.

Participants/Inclusion and exclusion criteria
Inclusion criteria: iranian, literacy, at least one year has passed since menopause, in the first ten years of menopause, having sexual activity, not using hormone therapy and chemical and herbal drugs affecting sexual function, without surgical histories such as hysterectomy, oophorectomy, cystocele, and rectocele. Exclusion criteria: unwillingness to continue participating in the research, cessation of sexual activity.

Intervention groups
The intervention group will have two individual counseling sessions of 60 to 90 minutes, one week apart. In the first session, the first three stages of the model, including bring up, explain, and tell, will be implemented. In the second session, the next three stages, including time, education, and record, will be implemented. The control group, will not receive counseling based on the BETTER model and the usual care will be provided along with the pamphlet prepared by the research team.

Main outcome variables
Sexual function; Dysfunctional sexual beliefs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150128020854N12**
Registration date: **2023-10-12, 1402/07/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-12, 1402/07/20**
Update count: **0**

Registration date
2023-10-12, 1402/07/20

Registrant information
Name
Hedyeh Riazi
Name of organization / entity
Shahid Beheshti University of Medical Science
Country
Iran (Islamic Republic of)
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Email address
h.riazi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sexual counseling based on the BETTER model on sexual function and sexual dysfunctional beliefs in postmenopausal women referred to comprehensive health services affiliated to Shahid Beheshti University of Medical Sciences

Public title

The effect of sexual counseling based on the BETTER model on sexual function and sexual dysfunctional beliefs in postmenopausal women referred to comprehensive health services affiliated to Shahid Beheshti University of Medical Sciences

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1- At least one year has passed since the last menstruation. 2- Being in the first ten years of menopause. 3- Have sexual activity. 4- Do not use hormone replacement therapy. 5- Have not undergone hysterectomy, oophorectomy, cystocele, rectocele, and mastectomy. 6- Their spouses do not suffer from sexual problems. 7- Do not use chemical or herbal drugs effective on sexual function. 8- Premature menopause has not happened. 9- Do not suffer from depression, anxiety, and stress (according to the results of the DASS questionnaire).

Exclusion criteria:

1_ Unwillingness to continue participating in the study. 2_ Interruption of sexual activity during the study for any reason (such as illness, death of spouse).

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

First, two centers will be randomly selected from the comprehensive health service centers affiliated to Shahid Beheshti University of Medical Sciences. Then randomly one center will be assigned to the intervention group, and one center will be assigned to the control group by lottery. Then, from the medical record numbers of the women who meet the inclusion criteria, 53 people will be selected in each center by lottery. Based on the lottery in the control center, those whose last digit of their file number is odd and in the intervention center those whose last digit of their file number is even will enter the study after the lottery.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences, School of Nursing and Midwifery

Street address

Vali-e-Asr St - Niayesh Intersection- In front of Shshid Rajaei Heart Hospital- School of Nursing and Midwifery

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.070

Health conditions studied

1

Description of health condition studied

Sexual counselling

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sexual function

Timepoint

Before the intervention, 4 week after intervention

Method of measurement

Female sexual function index

2

Description
Dysfunctional sexual beliefs
Timepoint
Before the intervention, 4 week after intervention
Method of measurement
A self-designed questionnaire for dysfunctional sexual beliefs

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the women of the intervention group will have two individual counseling sessions of 60 to 90 minutes, one week apart. The content of the sessions is based on the sexual problems raised by women, which will be implemented according to the BETTER model. The first session: The purpose of this session is to create a sense of security and peace in the client and to normalize sexual discourse and reduce the client's sense of shame. The counselor simply talks about sexual issues with the client and tells them that he can talk quite easily. In fact, normalization of the problem is done in this step (first step, Bring up). Then the consultant talks to the client about the importance and impact of sexual issues, especially after menopause, on the quality of life, and gives brief explanations about the function of the sexual organs after menopause and common problems during this period, and about the fact that not treating sexual problems is possible. has effects on married life, gives explanations and it will be said that the client is completely free to talk about this. Then, by asking a few open questions about the client's sexual problem and concern, he will be asked if he has ever discussed this with his wife, thus encouraging the client to talk (second step, explain). Then solutions are given according to their main problem and the counselor assures the client that he will provide all the necessary information to solve his problem (third stage, tell). At the end of the session, the client is asked to discuss his sexual concerns with his wife and list his sexual problems again. At the same time, apply the provided solutions. The second session: The purpose of this session is to increase the client's sense of confidence in the availability of the counselor and to increase the ability to manage sexual problems by herself, as well as to correct misconceptions related to sexual issues after menopause. First, it is requested to express the result of the action regarding the solutions presented in the previous session, especially the conversation with her husband, and express her sexual problems again, and then according to the prioritization of the problems, the duration of the consultation is based on the preference and readiness of the client. It is determined and since the restoration of sexual relationship is an ongoing process, the counselor will be available to address the concerns and answer the client's questions. For this purpose, the researcher will answer their questions by providing them with a contact number at specific hours (fourth step, time). In this meeting, which is held according to the client's preparation and request, the consultant first asks the client's opinion about the previous meeting and the effect of the proposed solutions to be recorded in his file. The counselor is informed by the client's knowledge about how to deal with sexual problems after menopause, so he is asked which of the strategies he used to solve the problem was effective and in order to correct the misconceptions about intimacy after menopause. Menopause is attempted (stage 5, education). Then the counselor provides more complete training about the client's sexual problem. (Continuation of the training of the first session). In the sixth stage of the BETTER model,(stage 6, Record), evaluations, interventions and treatment outcomes of the client are recorded. Women's sexual function questionnaires (FSFI) and sexual dysfunctional beliefs were made by the researcher before the intervention and 4 weeks after the end of the intervention by the company. will be completed.
Category
Other

2

Description
Control group: for the control group, no intervention with the BETTER model will be carried out during the research, and only the usual interventions and the presentation of pamphlets prepared by the research team will be carried out, but after the end of the research, they will be invited to receive advice based on the above model.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Pardis comprehensive health service center
Full name of responsible person
Elnaz Ariafar
Street address
Edalat square, South Farvardin St, Behind Imam Ali Mosque
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2

Recruitment center

Name of recruitment center
Boumehen comperehensive health servises center

Full name of responsible person
Elham Najafi

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Province
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Negin Bahri

Position
Midwifery Master Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Associate Professor

Latest degree
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Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
If there is a logical reason, it will be provided to the journal for publication of the article.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Demographic characteristics and findings related to the main outcome variable will be published in the paper.
When the data will become available and for how long
After the publication of the paper
To whom data/document is available
Researchers
Under which criteria data/document could be used
other statistical analysis
From where data/document is obtainable
Dr. Hedyeh Riazi h.riazi@sbmu.ac.ir
What processes are involved for a request to access data/document
After counseling with the research team, the data will be provided to the applicant, which will be probably a one-month process
Comments